

REMARKS

A. Status of the Claims

Claims 1, 5-8, 11, 12, 25-27, 32, 33, 36-37, and 40-43 are pending in this application. Claims 1, 2, 5-8, 11, 12, 25-27, 32, 33, 36 and 37 have been rejected. Claims 1, 5, 7, 8, 11, 12, 36, 37, and 40-42 have been amended. Claim 2 has been cancelled. Claim 43 has been added. Prior to this amendment, Claims 40-42 were allowed.

B. Oath / Declaration

At page 3 of the Office Action, the Examiner states that the Declaration fails to comply with 37CFR 1.497(a)(2) since PCT/US03/34345 filed October 28, 2003 is not identified in the Declaration.

Applicants respectfully disagree. As the Examiner notes, under 37CFR 1.497(a)(2), Applicants must identify "...the specification to which it is directed". In addition, under 37CFR 1.497(c), the Declaration must satisfy 37 CFR 1.63. Applicants respectfully submit that their declaration does both. Specifically, the Declaration identifies the specification as the one which "bears the Attorney Docket Number and Title of the invention noted above." Thus, the Declaration identifies the specification as the one which bears the Attorney Docket Number 21186Y and Title CARBONYLAMINO-BENZIMIDAZOLE DERIVATIVES AS ANDROGEN RECEPTOR MODULATORS.

As documented by the enclosed copy of the bibliographic data provided in the public PAIR system, the Patent office has acknowledged that the PCT application in question bears the Attorney Docket Number 21186Y. Moreover, given that the PCT application in question was originally filed in the US Receiving Office, the Examiner will be able to confirm that the PCT application, as filed, bears the Docket Number 21186Y in the upper left hand corner of each page. Given that the Declaration also provides the names of the inventors and their citizenship, Applicants respectfully submit that the Declaration also satisfies 37 CFR 1.63.

C. Rejection of Claims under 35 U.S.C § 112 2nd Paragraph

At page 4 of the Office Action, the Examiner rejects claims 1, 2, 5-8, 11, 12, 25-27, 32, 33, 36 and 37 under 35 USC 112, second paragraph as being indefinite. The Examiner states:

"In claim 1, R³ and R⁴ representing an 'oxo' group makes claim 1 indefinite because each of R³ and R⁴ are substituted on an aryl which introduces a valence problem. See claims 2 and 6 for same.

In claim 1, under the definition of R^b, it is unclear what the substituent '(O)₂R^a' represents. See claim 2 for same.

In claim 8, an 'and' is needed before '(C₁₋₃)perfluoroalkyl' for proper Markush language format.

In claims 11, 12, 36 and 37, an 'and' is needed before the last compound listed in each of these claims."

In response, Applicants have amended the Claims as indicated by the Examiner. Applicants respectfully submit that their amendments to the claims render these issues moot.

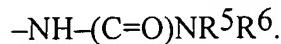
D. Rejection of Claims under 35 U.S.C § 102(b)

At page 6 of the Office Action, the Examiner rejects 1, 2, 5-8, 11, 12, 25-27, 32, 33, 36 and 37 under 35 USC 102(b) as being anticipated by Hoff et al. or Jemison et al. Examiner states:

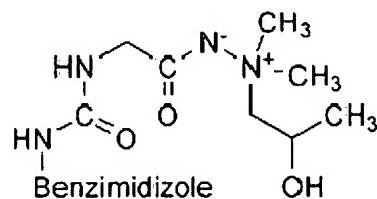
"Claims 1, 2, 5-8, 25, 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by:

- a) Hoff et al. {U.S. Pat. 3,743,738} – see, for instance, Example 57 in column 25; or
- b) Jemison et al. {AU 519,236} – see Compound 20 on page 30, lines 4-5."

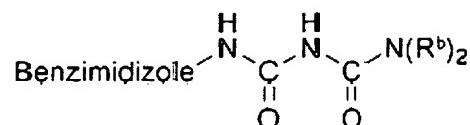
Applicants respectfully submit that the rejection based on Jemison is misplaced. A reference under § 102(b) must disclose each and every limitation of the claimed invention. Jemison fails to do this. For example, in Applicant's compounds, R² is -(C=O)NR⁵R⁶. Thus, the left hand side of Formula I must bear the substituent:



In contrast, (and ignoring the charge) Compound 20 on page 39 of Jemison bears the substituent:



While one of Applicants R⁵ and R⁶ can provide the hydrogen in bold, the remaining portion of Jemison (-CH₂(C=O)-N-N(CH₃)₂(CH₂CH(OH)CH₃) cannot be provided by R⁵ or R⁶ (as shown below).



Applicants respectfully submit that their amendments to the claims render this issue moot with regard to Hoff et al. Support for these amendments is found in the original Claims, as well as in numerous examples, specifically, examples 2-10 to 2-26, and examples 2-53 to 2-59.

E. Rejection of Claims under 35 U.S.C § 103(a)

At page 7 of the Office Action, the Examiner rejects 1, 2, 5-8, 11, 12, 25-27, 32, 33, 36 and 37 under 35 USC 103(a) over Hoff et al. (US 3,743,738). The Examiner states:

Applicant claims benzimidazole compounds. Hoff et al. (see entire document; particularly columns 2-4, 14 and 15; and especially Example 57 in column 25) teach benzimidazole compounds that are either structurally the same as (see above 102 rejection) or structurally similar to the instant claimed compounds.

The indiscriminate selection of 'some' among 'many' is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., anthelmintics).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful as anthelmintic agents. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

Examiner's reference to *In re Lemin* is inappropriate. 141 USPQ 814 (1964). There, the Court emphasized that the Office rejected Lemin's claims as obvious because "Lemin has done no more than pluck a subgenus out of a generic disclosure by Jones, and has used that subgenus in precisely the manner taught by Jones." There, Lemin based his "discovery" on the fact that some of the compounds that fell within the prior art genus, had some "special significance." Here, the species claimed by Hoff are hardly the same as those in the instant invention (see 102(b) discussion above). Moreover, the compounds of the instant invention are useful as selective androgen receptor modulators, whereas the compounds of Hoff are allegedly useful as anthelmintics.

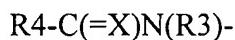
A 35 U.S.C. § 103(a) rejection requires that the prior art when combined must render the present invention *as a whole* obvious at the time it was made. (emphasis added). Here, the Examiner lists only a single reference. As stated in the M.P.E.P. § 2144.03, official notice unsupported by documentary evidence should only be taken by the Examiner where the facts are "capable of such instant and unquestionable demonstration as to defy dispute." Assertions

of specific knowledge of the prior art "must always be supported by citation to some referenced work recognized as standard in the pertinent art." (citing *In re Alehert*, 424 F.2d at 1091). In *Zurko*, the Court stated that it is never appropriate to rely solely on "common knowledge in the art" without evidentiary support in the record as the principal evidence upon which the rejection is based. 258 F.3d at 1385. Furthermore, the scope of the present invention is directed towards compounds useful for treating various diseases with selective androgen receptor modulators, not anthelmintics as in the reference cited by the Examiner.

Here, Examiner has two potential bases for a § 103(a) rejection - neither of which have been met. First, Examiner could provide support for the assertion that the compounds of the instant invention are obvious as anthelmintics. Second, Examiner could provide support for the assertion that the compounds of the instant invention are obvious as selective androgen receptor modulators. Here, the Examiner has not provided support for either assertion.

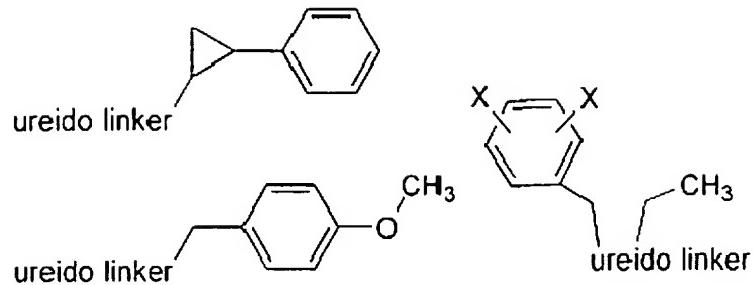
Furthermore, the Federal Circuit recently reasoned in *Takeda Chem. Indus., Ltd.* that "a case of *prima facie* obviousness with respect to chemical compounds requires a showing that the prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention." 492 F.3d 1350 (Fed. Cir. 2007) (citing *In re Deuel*, 51 F.3d 1552, 1558 (Fed. Cir. 1995)). The court made it clear that "consistent with the legal principles enunciated in KSR," there must be "some reason that would have led a chemist to modify a known compound in a particular manner."

It is acknowledged that the substituent on the left hand side of Hoff Formula I can be:



And that Hoff teaches, that among many of their choices, R^4 can be unsubstituted monoloweralkylamino, diloweralkylamino, or cycloalkylamino. However, no other choices are either taught or suggested. Equally important, there is no suggestion that such compounds would be useful as anthelmintics or as selective androgen receptor modulators.

None of the choices taught or suggested by Hoff are possible in the present invention. For example, in the instance when R^6 is an alkyl, that alkyl must be substituted, with, for example,



Applicants respectfully traverse and submit that their amendments to the claims render this issue moot with regard to Hoff et al. Support for these amendments is found in the original claims and in numerous examples, specifically, 2-19 to 2-22, and 2-53 to 2-64.

F. Summary

At page 9 of the Office Action, the Examiner states that claims 40-42 are allowed over the art of record.

Having addressed the outstanding issues, Applicants respectfully request early examination and allowance of the claims. The Examiner is invited to contact the undersigned attorney at the telephone number provided below if such would advance the prosecution of this application. Applicant believes no additional fees are due, but the Commissioner is authorized to charge any fees required in connection with this response to Merck Deposit Account No. 13-2755.

Respectfully submitted,

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